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Substitute for form 1449A/PTO  <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANTS</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	09/863,816
				Filing Date	May 23, 2001
				First Named Inventor	LaColla et al.
				Group Art Unit	1623
				Examiner Name	Traviss C. McIntosh
Sheet	1	of	1	Attorney Docket Number	06171.105027 (IDX 1006 US)

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicants of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/Relevant Figures Appear
		Number	Kind Code (if known)			
	AA	2003/0008841	A1	Devos et al.	01-09-2003	
	AB	2003/0028013	A1	Wang et al.	02-06-2003	
	AC	2003/0083307	A1	Devos et al.	05-01-2003	
	AD	2003/0087873	A1	Stuyver et al.	05-08-2003	

FOREIGN PATENT DOCUMENTS								
Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicants of Cited Document	Date of Publication of Cited Document DD-MM-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Office <sup>3</sup>	Number	Kind Code <sup>2</sup> (if known)				
	AE	WO	03/061385	A1	RIBAPHARM INC.	07-31-2003		
	AF	WO	03/062255	A2	RIBAPHARM INC.	07-31-2003		
	AG	WO	03/068162	A2	PHARMASSET LTD.	08-21-2003		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	AH	BAGINSKY, S.G. et al., "Mechanism of action of a pestivirus antiviral compound" PNAS USA 2000, 97(14), 7981-7986.	

Examiner Signature		Date Considered	3/15/2004
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicants.

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Submitted for form 1449/PTO <b>SUPPLEMENTAL          INFORMATION DISCLOSURE          STATEMENT BY APPLICANT</b>				<b>Complete if Known</b>	
				Application Number	09/864,078
				Filing Date	23 May 2001
				First Named Inventor	Sommadossi, J-P. et al.
				Group Art Unit	1614
Sheet	1	of	6	Attorney Docket Number	06171.105022.

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document Number Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pgs, Clmns, Lns, Where Relevant Passages/Relevant Figs Appear
		5,977,061	Antonin Holy		

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Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document Office <sup>3</sup> Number Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document DD-MM-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>4</sup>
		WO 99/43691 A	CHOI et al	2 Sep 1999		
		GB 1 209 654 A	Merck & Co. Inc.	21 Oct 1970		
		JP 1 521 076 A	Merck & Co. Inc.	12 Apr 1968		
		GB 1 163 103 A	Merck & Co. Inc.	4 Sep 1969		
		JP 2 662 165 A	Univ Paris Curie	22 Nov 1991		

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<sup>1</sup>Unique citation designation number. See attached kinds of U.S. Patent Document. <sup>2</sup>Kind of document. <sup>3</sup>Office of origin. <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate authority.

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Submitted for form 1-4 PTO JUL 1 2003 <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Complete if Known</b>		
				Application Number	09/863,816	
				Filing Date	23 May 2001	
				First Named Inventor	Sommudossi, J-P.	
				Group Art Unit	1614	
Attorney Docket Number	06171.105027					
Sheet	1	of	6			

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		Number	Kind Code (if known)			
<i>P</i>	A	6,395,716		Novirio Pharmaceuticals Limited	28 May 2002	
<i>P</i>	B	6,444,652		Novirio Pharmaceuticals Limited	03 September 2002	
<i>W</i>	C	6,340,690		Bio-Chem Pharma, Inc.	02 January 2002	

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		Office <sup>2</sup>	Number	Kind Code <sup>2</sup> (if known)			
<i>P</i>	D	WO	01/96353		Novirio Pharmaceuticals Limited	20 December 2001	
<i>P</i>	E	WO	00/09531		Novirio Pharmaceuticals Limited	24 February 2000	
<i>P</i>	F	WO	01/60315	A3	Shire Biochem Inc.	23 August 2001	
<i>P</i>	G	WO	01/90121		Novirio Pharmaceuticals Limited	29 November 2001	
<i>P</i>	H	WO	01/91737		Novirio Pharmaceuticals Limited	29 May 2001	
<i>P</i>	I	WO	02/057287	A2	Merck & Co. Inc.	25 July 2002	
<i>P</i>	J	WO	02/057425	A2	Merck & Co. Inc.	25 July 2002	
<i>P</i>	K	WO	02/070533	A3	Pharmasset LTD.	12 September 2002	

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1 2003 SUPPLEMENTAL  
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STATEMENT BY APPLICANT

Sheet	2	of	6
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Application Number	09/863,816
Filing Date	23 May 2001
First Named Inventor	Sommadossi, J
Group Art Unit	1614
Attorney Docket Number	06171.105027

## FOREIGN PATENT DOCUMENTS

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		Office	Number	Kind Code <sup>2</sup> (if known)			
(L)	L	WO	02/094289	A1	F. Hoffmann-La Roche AG	28 November 2002	
(M)	M	WO	02/100415	A2	F. Hoffmann-La Roche AG	19 December 2002	
(N)	N	WO	02/18404	A2	F. Hoffmann-La Roche AG	07 March 2002	
(O)	O	WO	02/32920	A2	Pharmasset LTD.	25 April 2002	
(P)	P	WO	03/026675		Idenix Pharmaceuticals Inc.	04 March 2003	
(Q)	Q	WO	01/16671		Novirio Pharmaceuticals Limited	23 May 2001	
(R)	R	WO	03/26589		Idenix Pharmaceuticals Inc.	04 March 2003	
(S)	S	GB	1 163 103	A	Merck & Co. Inc.	04 September 1969	
(T)	T	GB	1 209 654	A	Merck & Co. Inc.	21 October 1970	
(U)	U	FR	1 521 076	A	Merck & Co. Inc.	12 April 1968	
(V)	V	FR	2 662 165	A	Univ Paris Curie	22 November 1991	
(W)	W	WO	01/16671		Novirio Pharmaceuticals Limited	23 May 2001	
(X)	X	WO	02 48165	A2	Pharmasset LTD.	17 December 2001	
(Y)	Y	WO	01/79246		Pharmasset LTD.	13 April 2001	

Table 1. Population size, number of cases, and number of deaths due to cancer in the United States, 1990-1999, by age group and sex. The population size is based on the 1990 US Census, and the number of cases and deaths is based on the 1990-1999 data from the Surveillance, Epidemiology, and End Results (SEER) program. The population size is based on the 1990 US Census, and the number of cases and deaths is based on the 1990-1999 data from the Surveillance, Epidemiology, and End Results (SEER) program.



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Sheet	4	of	6		

Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
AJ	AJ	FRANCHETTI <i>et al.</i> <u>J. Med. Chem.</u> , <b>1998</b> , <i>41</i> , 1708	
	AK	GROUILLER <i>et al.</i> <u>Synlett</u> , <b>1993</b> , 221	
	AL	HARAGUCHI <i>et al.</i> <u>Tetrahedron Letters</u> , <b>1991</b> , <i>32</i> , No. 28, 3391	
	BA	HARRAGUCHI <i>et al.</i> <u>Nucleosides &amp; Nucleotides</u> , <b>1995</b> , <i>14</i> , 417	
	BB	HATTORI <i>et al.</i> <u>J. Med. Chem.</u> , <b>1998</b> , <i>41</i> , 2892	
	BC	IINO <i>et al.</i> <u>Nucleosides and Nucleotides</u> , <b>1996</b> , <i>15</i> , 169	
	BD	ITOH <i>et al.</i> <u>J. Org. Chem.</u> , <b>1995</b> , <i>60</i> , 656	
	BE	JOHNSON <i>et al.</i> <u>Nucleosides &amp; Nucleotides</u> , <b>1995</b> , <i>14</i> , 185	
	BF	LAVAIRE <i>et al.</i> <u>Nucleosides &amp; Nucleotides</u> , <b>1998</b> , <i>17</i> , 2267	
	BG	KAWANA <i>et al.</i> <u>Nucleic Acids Symp. Ser.</u> , <b>1986</b> , <i>17</i> , 37	
	BH	MATSUDA <i>et al.</i> <u>Chem. Pharm. Bull.</u> , <b>1987</b> , <i>35</i> , 3967	
	BI	MATSUDA <i>et al.</i> <u>Chem. Pharm. Bull.</u> , <b>1988</b> , <i>36</i> , 945	
BJ	BJ	MATSUDA <i>et al.</i> <u>J. Med. Chem.</u> , <b>1991</b> , <i>34</i> , 234	
	BK	MATSUDA <i>et al.</i> <u>Nucleosides &amp; Nucleotides</u> , <b>1992</b> , <i>11</i> , No. 24, 197	
BL	BL	MIKHAILOV <i>et al.</i> <u>Carbohydrate Research</u> , <b>1983</b> , <i>124</i> , 75	

### Discussion

1800

3/5/2004

have been previously documented in the literature (see, for example, Kohn et al., 1998; Goss et al., 1999; Denny et al., 2000). In this study, we use the patient's name, address, and date of birth to identify patients in the Medicare database. We use the patient's date of birth to identify the patient in the state of Florida and the Empson must provide the serial number of the patient document. Kind 4 documents are the appropriate controls for patients in the Medicare and WIPD database. Kind 4 documents are not subject to the same review process as Kind 1 documents. Kind 4 documents are subject to a review process that is less rigorous than the review process for Kind 1 documents.

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Application Number **09/863,816**  
Filing Date **23 May 2001**  
First Named Inventor **Sommadossi, J-P. et al.**  
Group Art Unit **1614**  
Attorney Docket Number **06171.105027.**

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
(b)	BM	MIKHAILOV <i>et al.</i> <u>Nucleosides &amp; Nucleotides</u> , <b>1991</b> , <i>10</i> , 339	
	BN	MIKHAILOV <i>et al.</i> <u>J. Org. Chem.</u> , <b>1992</b> , <i>57</i> , 4122	
	CA	OIVANEN <i>et al.</i> <u>J. Chem. Soc. Perkin Trans.</u> , <b>1994</b> , <i>2</i> , 309	
	CB	ONG <i>et al.</i> <u>Biochemistry</u> , <b>1992</b> , <i>31</i> , 11210	
	CD	ROGERS <i>et al.</i> <u>Nucleosides &amp; Nucleotides</u> , <b>1997</b> , <i>16</i> , 1457	
	CE	ROSENTHAL <i>et al.</i> <u>Carbohydrate Research</u> , <b>1980</b> , <i>79</i> , 235	
	CF	SAMANO <i>et al.</i> <u>J. Am. Chem. Soc.</u> , <b>1992</b> , <i>114</i> , 4007	
	CG	SAMANO <i>et al.</i> <u>Can. J. Chem.</u> , <b>1993</b> , <i>71</i> , 186	
	CH	SERAFINOWSKI <i>et al.</i> <u>Tetrahedron, Elsevier Science Publishers</u> , <b>1999</b> , <i>56</i> , No. 2, 333	
	CI	SHARMA <i>et al.</i> <u>Nucleosides, Nucleotides and Nucleic acids</u> , <b>2000</b> , <i>19</i> , No. 4, 757	
	CJ	TRITSCII <i>et al.</i> <u>Bioorganic &amp; Medicinal Chemistry Letters</u> , <b>2000</b> , <i>10</i> , 139	
	CK	TUNITSKAYA <i>et al.</i> <u>Febs Letters</u> , <b>1997</b> , <i>400</i> , 263	
	CL	USUI, <i>et al.</i> <u>Chem. Pharm. Bull.</u> , <b>1986</b> , <i>34</i> , 15	
	CM	WALCZAK <i>et al.</i> <u>Acta Chemica Scand.</u> , <b>1991</b> , <i>45</i> , 930	
	CN	WALTON <i>et al.</i> <u>J. Med. Chem.</u> , <b>1969</b> , <i>12</i> , 306	

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First Named Inventor				Sommadosi, J-P. et al	
Group Art Unit				1614	
Attorney Docket Number				06171.105027.	
Sheet	6	of	6		

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No date &  
not received.

*James*

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1. The patent document is in French. See French Patent Document No. 1,197,000. The French text is used as the basis for the English and WPT texts. 2. In these patent documents, the indication of the year of the filing of the patent document is given in the French text of the WPT document. 3. The Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbol. 4. A list of the French and French-English equivalents of the English language French translation is attached.



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Attorney Docket Number	06171.105027.					
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		Number	Kind Code (if known)			
PE	A	2002/0147160	A1	Merck and Co. Inc.	October 10, 2002	
TS	B	2003/0050229	A1	Novirio (Idenix Pharmaceuticals Inc.)	March 13, 2003	

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		Office <sup>3</sup>	Number <sup>2</sup>	Kind Code (if known)				
TS	C	WO	03/051899 A1	A1	Ribapharm Inc.	26-06- 2003		

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				Attorney Docket Number	NOV 1006 06171.105027
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		Number	Kind Code (if known)			
CP	AA	5,977,061		De Clercq	11/02/99	

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	09/863,816
		Filing Date	May 23, 2001
		First Named Inventor	LaColla <i>et al.</i>
		Group Art Unit	1614
		Attorney Docket Number	NOV 1006 06171.105027
Sheet	2	of	2

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	BA	BAGINSKI S. G. <i>et al.</i> "Mechanism of action of a pestivirus antiviral compound" PNAS USA 2000, 97(14), 7981-7986	
(B)	BB	FARKAS, J., <i>et al.</i> , "Nucleic acid components and their analogues. XCIV. Synthesis of 6-amino-9-(1-deoxy- $\beta$ -D-psicofuranosyl)purine" <i>Collect. Czech. Chem. Commun.</i> 1967, 32, 2663-2667	
(B)	BC	FARKAS, J., <i>et al.</i> , <i>Collect. Czech. Chem. Commun.</i> 1966, 31, 1535-1543	
(B)	BD	H. HREBACEKY <i>et al.</i> , <i>Collect. Czech. Chem. Commun.</i> 1972, 37, 2059-2065	
(B)	BE	H. HREBACEKY <i>et al.</i> , <i>Collect. Czech. Chem. Commun.</i> 1974, 39, 2115-2123	
(B)	BF	HARRY-O'KURU, <i>et al.</i> , "A short, flexible route toward 2'-C-branched ribonucleosides", <i>J. Org. Chem.</i> 1997, 62, 1754-1759	
(B)	BG	LEYSEN, P. <i>et al.</i> , <i>Clinical Microbiology Reviews</i> , Washington, D.C., (2000-01), 13(1), 67-82	
(B)	BH	MARTIN, X., <i>et al.</i> , <i>Tetrahedron</i> , 1994, 50, 6689-6694	
(B)	BI	NUTT, R.F., <i>et al.</i> , "Branched-chain sugar nucleosides. III. 3'-C-methyladenine," <i>J. Org. Chem.</i> 1968, 33, 1789-1795	
(B)	BJ	PAN-ZHOU X-R, <i>et al.</i> , "Differential effects of antiretroviral nucleoside analogs on mitochondrial function in HepG2 cells" <i>Antimicrob Agents Chemother</i> 2000; 44:496-503	
(B)	BK	SOMMADOSSI J-P, <i>et al.</i> , "Toxicity of 3'-azido-3'-deoxythymidine and 9-(1,3-dihydroxy-2-propoxymethyl)guanine for normal human hematopoietic progenitor cells in vitro" <i>Antimicrobial Agents and Chemotherapy</i> 1987; 31:452-454	
(B)	BL	SOMMADOSSI J-P, <i>et al.</i> , "Comparison of cytotoxicity of the (-) and (+)-enantiomer of 2',3'-dideoxy-3'-thiacytidine in normal human bone marrow progenitor cells" <i>Biochemical Pharmacology</i> 1992; 44:1921-1925	

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